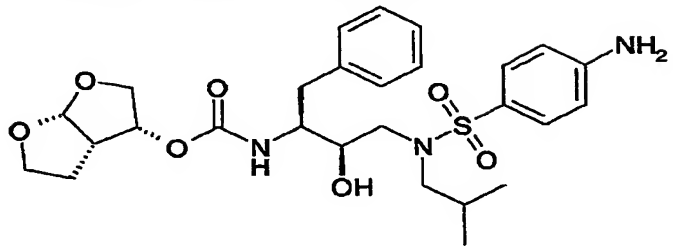
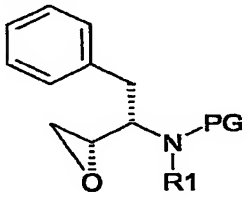
CLAIMS

1. A process for preparing compound of formula (6),



addition salts, polymorphic and/or pseudopolymorphic forms thereof; characterized in that said process comprises:

(i) introducing an isobutylamino group in compound of formula (1)



(1)

wherein

PG represents an amino-protecting group;

R_1 is hydrogen or C_{1-6}alkyl;

(ii) introducing a p-nitrophenylsulfonyl group in the resultant compound of step (i);

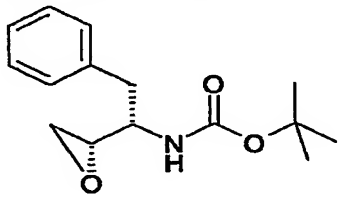
(iii) reducing the nitro moiety of the resultant compound of step (ii);

(iv) deprotecting the resultant compound of step (iii); and

(v) coupling the resultant compound of step (iv) with a (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl derivate.

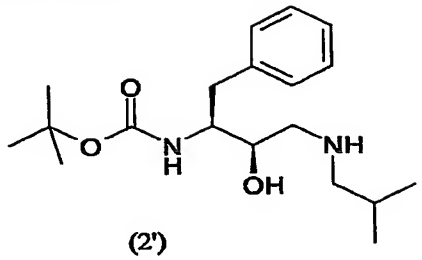
2. A process according to claim 1 for preparing compound of formula (6), characterized in that said process comprises the steps of:

introducing an isobutylamino group in compound of formula (1');



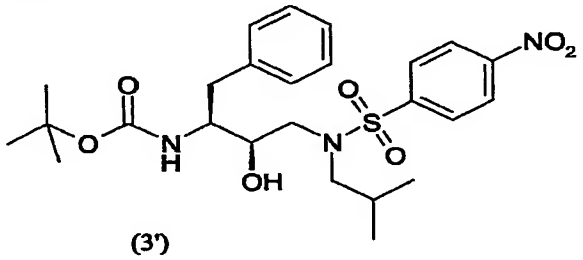
(1')

to obtain compound of formula (2');



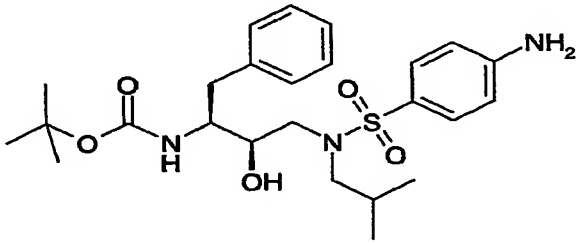
(2')

introducing a p-nitrophenylsulfonyl group into compound of formula (2') to obtain compound of formula (3');



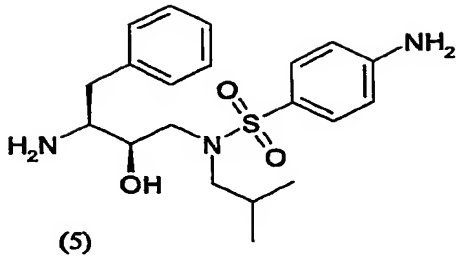
(3')

reducing the nitro moiety of compound of formula (3') to obtain compound of formula (4');



(4')

deprotecting compound of formula (4') to obtain compound of formula (5)



(5)

coupling compound of formula (5) with (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl derivate to obtain compound of formula (6).

3. A process according to any one of claims 1 to 2 wherein step (i) is carried out in toluene.

4. A process according to any one of claims 1 to 3 wherein step (ii) is carried out in toluene, ethylacetate, methylene chloride, dichloromethane, or tetrahydrofuran.

5. A process according to any one of claims 1 to 4 wherein step (iii) is carried out in the presence of up to 10 mol % primary or secondary amine, preferably ethanolamine, with palladium on charcoal under a hydrogen atmosphere.

6. A process according to any one of claims 1 to 5 wherein step (iv) is carried out in acidic or basic conditions.

7. A process according to any one of claims 1 to 6 wherein compound of formula (5) is crystallized by dissolving in a solvent system, adjusting the pH to a value higher than 9 and keeping the concentration of compound of formula (5) in solution in a value between 4% and 15% (w/w).

8. A process according to any one of claims 1 to 7 wherein compound of formula (5) is crystallized at a temperature between 0°C and 10°C.

9. A process according to any one of claims 7 to 8 wherein seed crystals of compound of formula (5) are added during crystallization.

10. A process according to any one of claims 7 to 9 wherein the solvent system comprises one or more water-miscible solvents and water.

11. A process according to any one of claims 7 to 9 wherein the solvent system comprises one or more water-immiscible solvents and water.

12. A process according to claim 10 wherein the solvent system is methanol, isopropanol, and water in a ratio 1:6.5:8 respectively.

13. A process according to any one of claims 1 to 12 wherein (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-ol or a precursor thereof is reacted with bis-(4-nitrophenyl)carbonate before coupling to compound of formula (5).

14. A process according to any one of claims 1 to 12 wherein (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-ol or a precursor thereof is reacted with disuccinimidyl carbonate before coupling to compound of formula (5).

15. A process according to claim 13 or 14 wherein the reaction of (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-ol or a precursor thereof and the carbonic acid derivative is activated by an (amine-) base, preferably triethylamine or pyridine.

16. Use of compound of formula (5), addition salts, polymorphic and/or pseudopolymorphic forms thereof for the preparation of compound of formula (6).

17. Use of compound of formula (5) according to claim 16, wherein compound of formula (5) is in the form of a free base.

18. Use of a compound according to any one of claims 1 to 17 as an intermediate for preparing compound of formula (6).